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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,050	06/20/2001	Liat Mintz	2786-0177P	2695

2292 7590 09/20/2002

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EXAMINER

JIANG, DONG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 09/20/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/884,050

Applicant(s)

MINTZ ET AL.

Examiner

Dong Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, 14-16, 18 and 19, drawn to an isolated nucleic acid, a vector containing same, a host cell thereof, classified in class 435, subclass 69.5.
- II. Claims 6-9, 20 part (a), 21, 22 part (a), and 23, drawn to a pharmaceutical composition comprising an expression vector, and a method for treatment using same (gene therapy), classified in class 514, subclass 44.
- III. Claims 10-12 and 24-26, drawn to a method for detecting a VEGF variant by hybridization, classified in class 435, subclass 6.
- IV. Claim 13, drawn to an isolated polypeptide, classified in class 530, subclass 351.
- V. Claim 17, drawn to an isolated antibody, classified in class 530, subclass 387.9.
- VI. Claims 20 part (b)-(d), and 21, drawn to a pharmaceutical composition comprising said polypeptide, or fragment or variants thereof, and a method for treatment using same, classified in class 424, subclass 85.1.
- VII. Claims 22 part (b), and 23, drawn to a pharmaceutical composition comprising an antibody, and a method for treatment using same, classified in class 424, subclass 139.1.
- VIII. Claims 27-29, drawn to a method for identifying a compound binding to said VEGF variant, and modulating the activity thereof, classified in class 435, subclass 7.1.
- IX. Claim 30, drawn to a method for detecting a VEGF variant using an antibody, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because:

The vector of Invention I and the method of gene therapy of Invention II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially

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different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed may be used for the recombinant production of the polypeptide of Invention IV.

Invention I is related to Invention III as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed may be used for the production of the polypeptide of Invention IV.

The nucleic acid of Invention I is related to the polypeptide of Invention IV by virtue of encoding same. The nucleic acid molecule has utility for the recombinant production of the protein in a host cell. Although the nucleic acid molecules and proteins are related since the nucleic acid encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the nucleic acid may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The nucleic acid of Invention I is distinct from and unrelated to the antibody of Invention V because they are physically and functionally distinct chemical entities which share neither structure nor function. Also, neither is required for the manufacture of the other.

Invention I is distinct from and unrelated to Inventions VI-IX, wherein the nucleic acid of Invention I is neither made by nor used in the methods of Inventions VI-IX, and wherein each does not require the other.

Inventions II, III, and VI-IX are drawn to independent methods, wherein each of the methods has different process steps, different subject, different active agent, different starting and ending points, and is for a different purpose, such that they require separate searches.

Invention IV is related to Inventions VI and VIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

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product (MPEP § 806.05(h)). In the instant case the product as claimed may be used for the production of the antibody of Invention V.

The polypeptide of Invention IV is related to the antibody of Invention V by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary steric complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or in assays for the identification of agonists or antagonists of the protein.

Invention IV is distinct from and unrelated to Inventions VII and IX, wherein the polypeptide of Invention IV is neither made by nor used in the methods of Inventions VII and IX, and wherein each does not require the other.

Invention V is distinct from and unrelated to Inventions VI and VIII, wherein the antibody of Invention V is neither made by nor used in the methods of Inventions VI and VIII, and wherein each does not require the other.

Invention V is related to Inventions VII and IX as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed may be used for the purification of the polypeptide of Invention IV.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matters, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

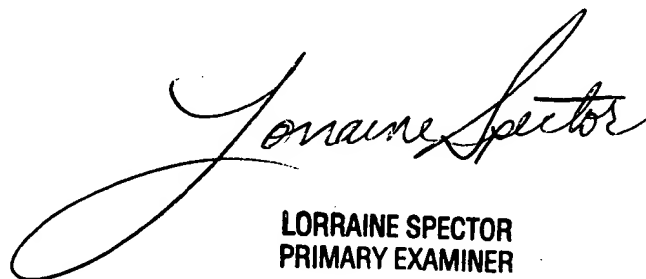
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Advisory Information

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



LORRAINE SPECTOR
PRIMARY EXAMINER

DJ
9/12/02